DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-22, 37-46, and 49-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling body weight reduction, does not reasonably provide enablement for prevention of body weight gain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the present instance, claims 15 and 41 recite the broad recitation 'in an EPA: DHA ratio from about 1:1 to 1:8, and the claim also recites 'in an EPA: DHA ratio from about 1:1 to 1:6, which is the narrower statement of the range/limitation.

> There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:
>
> (A) The breadth of the claims;
>
> (B) The nature of the invention;
>
> (C) The state of the prior art;
>
> (D) The level of one of ordinary skill;
>
> (E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Several factors discussed in regard to the *preventative* limitation in the instant claims are drawn primarily to the quantity of experimentation needed to make and/or use the invention based on the content of the disclosure. Based on adequate and substantive due experimentation, the amount of direction and guidance is determined in view of the scope of the claimed invention. The state of the prior art and predictability in the art are additional factors substantiated by the correlative data and cumulative results via experimentation and similar processes, *inter alia*, of the current invention. Finally the breadth of the claims in view of the claimed invention do not support nor suggest evidence of prevention.

The quantity of experimentation sufficient enough in order to determine a clear inventive objective drawn to preventative achievement is absent. The subject matter of the claimed invention is directed to a specific ratio formulation of EPA to DHA. The preferred embodiment of the invention is drawn to a method wherein the weight ratio of EPA: DHA in the fatty acid composition is 1: X, where X is equal or larger than 1. Further, the various dosage forms as disclosed that may comprise a dietary product **are not** presented with adequate elucidation to properly suggest to one of ordinary skill that there is possession of preventative achievement.

Accordingly, though animal models are reasonably representations drawn to determine safety and efficacy in humans, the experiments of the claimed invention directed to mice models do not support nor suggest a clear method of prevention in human subjects. The studies disclosed within the instant specification (pages 24-35) are replete with drug-regimen protocols which one of ordinary skill would readily determine to be a representative treatment in the reduction of the said disorder. However, the same seven studies in the instant specification do not adequately address the limitation drawn to prevention.

Thus, unpredictability will be high due to an unclear delineation in the claims in view of the distinction between the treating and the prevention/eradication of the said disorders. Furthermore, the term *prevention* is disclosed only twice in the entire specification (pg 1) but is absent of any definition, description, and/or explanation of prevention as it is presented in the instant claim set.

Summarily, the breadth of the claims is unclear in view of a scope of enablement for *prevention* of claimed invention. The specification does not substantiate due experimentation to determine preventative embodiments, i.e., comparative data and results, guidance in using in order to prevent, and predictability drawn to prevention.

For evidentiary purposes in regard to the state of the art drawn specifically to inadequacies of existing obesity treatments: The study by Zorrilla *et al.* (1) is also intriguing because of its unique approach to combating obesity. As its increasing prevalence suggests, obesity is quite difficult to prevent, manage, and reverse. Losing weight by dieting often results in rebound weight gain. Notably, such rebound weight gain has been proposed to be due in part to elevated ghrelin levels induced by the initial dieting-associated weight loss (27). Surgery is

effective, but is only indicated in individuals with body mass indices ≥40 or ≥35 with comorbid conditions (28, 29). Surgery also comes with significant risk (28). Medications currently approved for obesity are for treatment only, as opposed to prevention, and although they are effective for many people, on average, they do not result in the degree of weight loss ultimately desired. Vaccination as a means of neutralizing or sequestering small, nonviral, nonbacterial molecules circulating in the bloodstream is a novel approach and is currently being investigated in clinical trials as a treatment for drug addiction (Jeffrey M. Zigman et al., In search of an effective obesity treatment: A shot in the dark or a shot in the arm?, PNAS | August 29, 2006 | vol. 103 | no. 35 | 12961-12962, printed pages 1-7, especially page 3, 3rd paragraph).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-22, 37-39, 42- 45, and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Breivik et al. (USPN 5,502,077).

Breivik et al. teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the

total fatty acids. The compositions can be used for the [...] ***prophylaxis*** of multiple risk factors for cardiovascular diseases (abstract only).

Breivik et al. teach that present invention relates to a fatty acid composition comprising at least 80% by weight of omega-3 polyunsaturated fatty acids, wherein at least 75% by weight of the total fatty acids comprise omega-3 (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA)C 20:5 and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid (DHA) C 22:6 9column 1, lines 5-10).

Breivik et al. teach the same and exact preferred ratio limitation in the instant claims. The upgrading of the EPA fraction to obtain a weight ratio of EPA: DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain an EPA: DHA weight ratio of from 1:1 to 1:2 may be achieved in the molecular distillation stage. The method also provides the possibility of using supercritical fluid extraction and/or chromatography in the second stage with CO.sub.2 eventually containing a more polar modifier, such as ethanol, in order to concentrate the EPA and/or DHA fraction (column 3, lines 61-67; column 4, lines 1 and 2).

Breivik et al. teach fish oil which is of animal origin (column 1, line 38). This limitation of oil also anticipates the limitation in the claims drawn to a liquid form (claim 51).

Additionally, it is well-known in the art of pharmacy technology that consumable oil formulations may be extrapolated into emulsion formulations which are essentially oil in water formulations indicated for oral administration

Breivik further anticipates the claimed invention by teaching that this preferred ratio of EPA: DHA has an advantageous effect on risk factors for cardiovascular diseases (column 2, lines 50-67).

Breivik et al. teaches an esterified formulation comprising EPA: DHA (column 3, lines 24-39).

Thus Breivik et al. fully anticipates each and every element of the claimed invention drawn to the limitation of *prevention which encompasses prophylactic treatment* within instant claim 1 and all claims dependent from claim 1.

The subject matter is identical and interchangeable. The inventive objective of the claimed invention is specifically drawn to specific embodiments drawn to ratios of EPA: DHA. Accordingly, the inventive objective is adequately met and encompassed by the methods, teachings, modifications, and inherencies within the Breivik et al. reference. Additionally, the limitations of the instant claims drawn to preventing body weight gain, treatment for obesity, or an overweight condition are well-known in the pertinent art and to one of skill as risk factors for cardiovascular disease as disclosed in the Breivik et al. reference. Further as evidence and incorporated by reference, Breivik et al. (USPN 5945318) lends support to the propensity of a marine oil being incorporated into foodstuffs (which generically encompasses foodstuffs). As is well known, EPA and DHA are proving increasingly valuable in the pharmaceutical and food supplement industries in particular. These acids are found in relatively high concentrations in certain marine oils, but for many purposes it is necessary that the marine oils should be refined in order to increase the content of EPA and/or DHA to suitable levels, or to reduce the concentrations of, or even eliminate, certain other substances which occur naturally in the raw oil. For pharmaceutical and food purposes, for instance, it is necessary to substantially completely eliminate all the pesticide residues which commonly occur in marine oils, even those

derived from fish caught in sea areas quite remote from intensively cultivated land areas (abstract only). This reference by way of evidence supports the 'snack' limitation. Snacks are edible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-22, 41, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (USPN 5,502,077) in view of Corkey et al.

Breivik et al. teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids. The compositions can be used for the ***treatment*** [...] of multiple risk factors for cardiovascular diseases (abstract only).

Breivik et al. teach that present invention relates to a fatty acid composition comprising at least 80% by weight of omega-3 polyunsaturated fatty acids, wherein at least 75% by weight of the total fatty acids comprise omega-3 (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA)C 20:5 and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid (DHA) C 22:6 9column 1, lines 5-10).

Breivik et al. teach the same and exact preferred ratio limitation in the instant claims. The upgrading of the EPA fraction to obtain a weight ratio of EPA: DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain an EPA: DHA weight ratio of from 1:1 to 1:2 may be achieved in the molecular distillation stage. The method also provides the possibility of using supercritical fluid extraction and/or chromatography in the second stage with CO.sub.2 eventually containing a more polar modifier, such as ethanol, in order to concentrate the EPA and/or DHA fraction (column 3, lines 61-67; column 4, lines 1 and 2).

Breivik et al. teach fish oil which is of animal origin (column 1, line 38). This limitation of oil also anticipates the limitation in the claims drawn to a liquid form (claim 51).

Breivik further anticipates the claimed invention by teaching that this preferred ratio of EPA: DHA has an advantageous effect on risk factors for cardiovascular diseases (column 2, lines 50-67).

Breivik et al. teaches an esterified formulation comprising EPA: DHA (column 3, lines 2-39).

Breivik et al. does not go into specific detail as to risks of cardiovascular disease in view of the specific treatment thereof.

However, Corkey et al. essentially teach dietary products for infant child and adult nutrition which possess adequate levels and **ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids.** Consumption of these dietary products can contribute to the prevention of obesity in developing individuals and can contribute to a **reduction in body fat mass in individuals who are trying to loose weight or reduce body fat mass (e.g., obese individuals)**. A first preferred product is a dairy supplement or formulated dairy product for consumption by infants or children to prevent development of obesity. A second preferred product is a **dietary supplement** for persons combating unwanted weight gain or obesity. Also featured are methods of formulating these dietary products (abstract only).

Corkey et al. teach dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006].

Corkey et al. teach [...].Because the .omega.-3 long chain fatty acids (EPA:DHA) have been shown to efficiently inhibit fatty acid synthesis, it is proposed that mixing MCFA with a

small portion of EPA and DHA will synergize the positive effects of both types of fatty acids in reducing fat storage in adipose tissue and fat product [0121].

Corkey et al. teach a dietary regimen to be incorporated concomitantly with the said weight-reduction formulation. The present invention features dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006]; [0034].

Corkey et al. teach a triglyceride form of the formulation. A glyceride is an ester of glycerol (1, 2, 3-propanetriol) with acyl radicals of fatty acids and is also known as an acylglycerol. If only one position of the glycerol molecule is esterified with a fatty acid, a "monoglyceride" is produced; if two positions are esterified, a "diglyceride" is produced; and if all three positions of the glycerol are esterified with fatty acid a "triglyceride" or "triacylglycerol" is produced. A glyceride is called "simple" if all esterified positions contain the same fatty acid; or "mixed" if different fatty acids are involved. The carbons of the glycerol backbone are designated sn-1, sn-2 and sn-3, with sn-2 being in the middle and sn-1 and sn-3 being the ends of the glycerol [0033].

In reference to the deficiencies in Corkey et al.,

Thus, it would be *prima facie* obvious to one of ordinary skill in the art to at once recognize a reasonable expectation of success via the incorporating together the methods and teachings of Breivik et al and Corkey et al. Determining the scope and contents of the prior art in view of the immediate references *supra* has been reasonably assessed.

Consummately, the Breivik et al. reference teaches the current invention. The specificities drawn to a particular target population suffering from specific risks and disorders

associated with cardiovascular diseases in need of such formulations are adequately supported and taught by Corkey et al.

Accordingly, the level of ordinary skill in the pertinent art suggests well-known and well-established protocols which are sufficiently described, defined, and explained in the references above. As a result, the inventive objective of current invention is made obvious. In consideration of the objective evidence present in the current application, it would have been *prima facie* obvious to combine the references together in obviousness over the claimed invention.

In view of the differences, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the fatty acid composition for treating persons with obesity because it is well-established in the art that the administration of such supplements aid in the treatment of weight control. Based on the secondary reference, Corkey et al. teach ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids. Further, the said reference teaches consumption of these dietary products [which] can contribute to the prevention of obesity in developing individuals and can contribute to a reduction in body fat mass in individuals who are trying to loose weight or reduce body fat mass (e.g., obese individuals). Accordingly, the reference of Corkey et al. reads on dietary formulations of the said fatty acids.

Similarly, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a dietary composition either in the form of a snack or emulsion. Accordingly, the reference of Corkey et al. reads on dietary formulations of which the said fatty acids are comprised.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
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